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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,528	06/23/2000	Jan Eirik Ellingsen	06275-199001	9997

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EXAMINER
CULBERT, ROBERTS P

ART UNIT	PAPER NUMBER
1763	10

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/602,528	Applicant(s) ELLINGSEN ET AL.	
	Examiner Roberts Culbert	Art Unit 1763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-81* is/are pending in the application.

4a) Of the above claim(s) *11-15 and 55-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,16-54 and 65-81* is/are rejected.

7)☒ Claim(s) *65-67,69,71,73,75 and 77* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *08/446,675* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 4/14/03 have been fully considered, but are not persuasive.

Applicant has argued that the treatment of independent claims 1, 2, 8, 10, and 16-18 occurs without significant etching of the implant, whereas the reference JP 3-146679 teaches conditions that do achieve significant etching.

The argument is not persuasive because applicant has not defined the term "significant etching". Applicant stated that the surface may undergo minor morphological changes (Page 5, lines 14-16), but does not quantify these changes in an appreciable way, such as average feature size, that might distinguish over the prior art.

A comparison of the figures only shows that changes do occur in the surface morphology at a 0.2% concentration for a treatment time of 30-90 seconds. Applicant states that the surface treated for 30 seconds is only slightly affected (Page 11, Lines13-24) whereas the surface treated for 90 seconds is distinctly altered. The stated difference further confuses the meaning of "significant etching" since both examples fall within the claimed range of 10 seconds to 2 minutes.

Furthermore, the treatment conditions of the instant application and the cited reference overlap. The applicant has not provided any reason why, for example, immersion in a 1% HF solution for 30 seconds causes significant etching in the JP 3-146679 reference, yet the same process conditions do not cause the same results in the invention of the instant application.

Applicant has argued that the JP 3-146679 reference does not anticipate the independent claims of the instant application under U.S.C. 102 (b) because independent claims 1, 2, 8, 10, and 16-18 are limited to a single significant step by the "consisting essentially of " transitional phrase, whereas the JP 3-146679 reference describes a two-step process including a post treatment with H_2O_2.

The argument is not persuasive. The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463

(CCPA 1976). See MPEP 2111.03. The post-treatment suggested in JP 3-146679 does not materially affect the basic and novel characteristics of the claimed invention, i.e. the improved attachment of the titamium implant to bone tissue. The only purpose of the post-treatment is to reduce tissue irritation (Page 4, line 30).

Claim Objections

Claims 65-67, 69, 71, 73, 75, and 77 are objected to because of the following informalities: "of in bone tissue" is unclear. As a correction, "of the implant in bone tissue" is suggested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-10, 16-40 and 65-78 are rejected under 35 U.S.C. 102(b) as being anticipated by Japanese Patent JP 3146679 to Haruyuki.

Haruyuki teaches a method for treating the surface of a titanium biorepair implant and increasing the strength of the bond between bone tissue and the metallic implant. Haruyuki describes treatment of the titanium implant in a 1-6% solution of hydrofluoric acid for a time of 30 seconds to 3 minutes. It is assumed that that the hydrofluoric acid solution is free of sodium ions. It is assumed that the surface of the titanium implant is initially covered with a thin layer of titanium oxide because Haruyuki does not mention an oxygen-free environment.

Although Haruyuki stresses the use of a post treatment with hydrogen peroxide, the use of hydrofluoric acid alone is clearly contemplated in Comparative Example 2. The results described in Table No.1 indicate that post treatment is not needed to affect the surface properties. Note the values of Rz are the same for example 2 and comparative example 2. The purpose of the hydrogen peroxide post

treatment is to reduce tissue irritation (Page 4 Line 30). Haruyuki teaches that only slight changes in morphology are needed to increase the attachment strength of the implant. Haruyuki indicates that features with an average depth below 0.5 μm would have a small anchoring effect (Page 4 Lines 21-26).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 5 and 79-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haruyuki.

The above-cited dependent claims differ from Haruyuki only by specifying various concentration ranges.

A person having ordinary skill in the art at the time of the claimed invention would have found it obvious to modify Haruyuki by using different concentrations because same were known to be cause effective variables and routine experimentation would have been expected to optimize them. *In re* Boesch, 205 USPQ 215 (CCPA 1980).

Furthermore, Haruyuki teaches that indicates that features with an average depth below 0.5 μm would have a small anchoring effect (Page 4 Lines 21-26). This statement suggests that there is some improvement in implant-adhesion at HF concentrations below 1%.

One of ordinary skill in the art would have been motivated at the time of invention to use a concentration less than 1% to determine the point at which adhesion is improved over the adhesion produced without treatment.

Changes in temperature, concentrations, or other process conditions of an old process, do not impart patentability unless the recited changes are critical, i.e., they produce a new and unexpected result. The results produced by the cited ranges in claims 5 and 79-81 do not produce results that are new or unexpected, i.e. improved adhesion to bone tissue.

Claims 41-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haruyuki in view of the admitted prior art. As applied above, Haruyuki discloses the method of the invention substantially as claimed, but does not teach post treatment with a solution containing calcium ions. The admitted prior art (Page 7 Lines 10-15) describes post treatment with a solution of calcium ions.

It would have been obvious to one of ordinary skill in the art at the time of invention to treat the implant with a solution containing calcium ions, in order to determine biocompatibility of the implant.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roberts Culbert whose telephone number is (703) 305-7965. The examiner can normally be reached on Monday-Friday (7:30-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory Mills can be reached on (703) 308-1633. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

April 21, 2003

BENJAMIN L. UTECH
SUPERVISORY PATENT EXAMINER
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